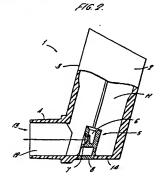
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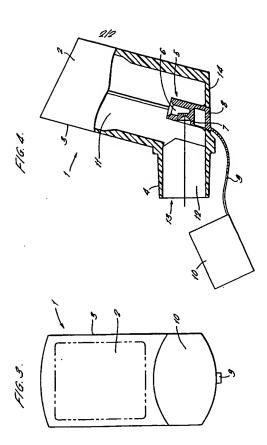
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(71) Applicant(s)	The second secon		
Bespek Pix	(56) Documents Cited		
. (Incorporated in the United Kingdom)	GB 2322804 A	GB 2170430 A	
Bergen Way, North Lynn Industrial Estats, KING'S LYNN, Norfelb, PE30 2JJ, United Kingdom	GB 1021739 A	WO 99/25406 A	
	US 2318908 A		
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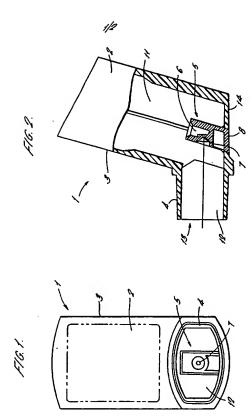
(54) Abstract Title

(57) The appearus comprises a housing (2) defining a socket or recess (1) for need-fing, in use, a pressurised dispensing container, further, a mountherce (4) and a valve starm receiving means (5) are provided. The valve stem receiving means edificing a bore (6) for need-ring in use a valve stem or a pressurised dispensing container, wherein the housing (2) is thronge from a form modding and the valve stem receiving means (5) is formed from a second moudding. The first and second mouddings are assemblable to form the dispensing appearus and may be secured together using snap-fit formations, mechanical flastners, adhebits or verificial. The mouddings may be made from different meterials and the second moulding may.



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IMPROVEMENTS IN OR RELATING TO DISPENSING APPARATUS

- 1 -

The present invention relates to a dispensing apparatus for use with pressurised dispensing containers and, in particular, but not exclusively, for an apparatus for dispensing orally inhaled medicinal products in aerosol form.

One type of pressurised dispensing container which is well known in the art is a pressurised metered dose inhaler which is used, for example, for the treatment of asthmatic conditions. Dispensing apparatuses are known for use with such pressurised metered dose inhalers which are generally known as actuators and are essentially as originally described in British Patents 830427 & 994755 and which comprise a housing including a generally upwardly projecting cylindrical portion defining a cylindrical recess or socket in which the pressurised metered dose inhaler is axially and slidably received. The housing further comprises a mouthpiece defining a generally horizontally extending air duct communicating with an outlet orifice of the mouthpiece. The tubular valve stem of the pressurised metered dose inhaler projects downwardly from the container and is sealingly received, in use, in a bore of a valve stem block situated at a lower end of the cylindrical recess or socket. The annular bore of the valve stem block contains a stop limiting the extent to which the valve stem may extend within the valve stem block. The valve stem block also comprises a spray orifice directed towards the outlet orifice of the mouthpiece. During use of the dispensing apparatus, the

pressurised metered dose inhaler is actuated by depressing the pressurised metered dose inhaler into the actuator such that a dose of product is dispensed into the bore of the valve stem block. The pressurised product is then directed laterally through the orifice to exit into the mouthpiece, in an aerosol form, from where it is inhaled by a user.

Such dispensing apparatus, comprising the cylindrical portion, mouthpiece and valve stem block, are made as a single piece moulding in order to minimise manufacturing costs.

There are, however, a number of problems with such one piece mouldings. Common problems include distortion of the moulding, either during the moulding step or on ejection of the moulding fron the mould tool: the presence of unwanted 'flash' on the edges of the moulding and difficulties in moulding sections having differing thicknesses due to uneven cooling characteristics.

The moulding of the valve stem block is critical to the performance of the apparatus since it controls the positioning of the pressurised dispensing container and the direction and spray pattern of the product dispensed through spray orifice 7. Additionally, the relative thickness of the valve stem block 5, compared to the rest of the housing 2, means that the moulding cycle time for the apparatus 1 is governed by the cooling and setting of the plastic in the region of the valve stem block 5, this to prevent distortion of this region after the moulding is ejected from the moulding tool. Since the moulding cycle time strongly influences the manufacturing cost of the apparatus, the moulding complexity of the valve stem block is a critical cost factor in the manufacture of the apparatus.

According to the present invention there is provided dispensing apparatus for use with a pressurised dispensing container comprising a housing defining a socket or recess for receiving, in use, a pressurised dispensing container; a mouthpiece; and a

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invention. The apparatus 1 comprises a housing 2, which includes a generally upwardly projecting cylindrical portion 3 and a mouthpiece 4.

The cylindrical portion 3 defines a cylindrical recess or socket 11 open at an upper end to receive a pressurised dispensing container (not shown) axially and slidably therein. A lower end of the cylindrical portion 3 is closed by a base wall 14. The pressurised dispensing container is a loose-fit in the socket 11 such that air can freely flow through the socket 11 in a peripheral space between the container and the housing wall.

The mouthpiece 4 extends laterally from a lower end of the cylindrical portion 3 and defines a horizontally extending air duct 12 communicating with an outlet orifice 13 at one end of the mouthpiece 4 and the socket 11 at the other end.

A vaive stem block 5 is located at the lower end of the cylindrical portion 3 mounted on or in base wall 14. The valve stem block 5 defines a bore 6 which, in use, receives a valve stem of the pressurised dispensing container. The bore 6 includes an annular shoulder which acts as a stop limiting the extent to which the valve stem may extend within the valve stem block 5.

The bore 6 of the valve stem block 5 communicates with a spray orifice 7 formed in a side of the valve stem block 5 facing the mouthpiece duct 12.

The dispensing apparatus 1 is designed for use with pressurised dispensing containers of the type having a valve located internally of the container, the valve being actuated by axial depression of the container causing the valve stem to move against internally provided spring bias to dispense a metered dose of product through the valve stem.

In use, actuation of the valve of the pressurised dispensing container causes a dose of pressurised

valve stem receiving means defining a bore for receiving, in use, a valve stem of a pressurised dispensing container; wherein the housing is formed from a first moulding and the valve stem receiving means is formed from a second moulding, the first and second mouldings being assemblable to form the dispensing apparatus.

There is also provided a method of manufacturing a dispensing apparatus for use with a pressurised dispensing container comprising the steps of making a first moulding which comprises a housing defining a socket or recess for receiving in use a pressurised dispensing container and a mouthpiece, making a second moulding which comprises a valve stem receiving means defining a bore for receiving in use a valve stem of a pressurised dispensing container, and assembling the first and second mouldings to form the dispensing apparatus.

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:-

Figure 1 is a front view of a first embodiment of dispensing apparatus in accordance with the present invention;

Figure 2 is a side view of the dispensing apparatus of Figure 1;

Figure 3 is a front view of a second embodiment of dispensing apparatus in accordance with the present invention with a cap in a first, closed position on a moutholece of the apparatus; and

Figure 4 is a side view of the dispensing apparatus of Figure 3 with the cap in a second, dispensing position.

Figures 1 and 2 show a first embodiment of dispensing apparatus according to the present

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product to be dispensed through the valve stem into the bore 6 of valve stem block 5. The product, which is still highly pressurised, is dispensed out of spray orifice 7 towards and into the mouthpiece duct 12 in an aerosol form from where it is inhaled by a user through the mouthpiece 4 at outlet 13.

According to the present invention, the generally cylindrical portion 3 and the mouthpiece 4 of the housing are formed as a first moulding and the valve stem block 5 is formed as a second moulding. The two mouldings are then assembled to form the apparatus 1.

The valve stem block 5 may be retained in or on the base wall 14 of the cylindrical portion 3 by any suitable means such as co-operating snap-fit formations 8 or by mechanical fastenings, adhesives, welds, or other known assembly techniques etc.

Figures 3 and 4 show a second embodiment of the present invention having a generally cylindrical portion 3, mouthpiece 4 and valve stem block 5 similar to that of the first embodiment. In the second embodiment, a cap 10 is provided for the mouthpiece 4 which cap 4 is attached to the valve stem block 5 moulding via a strap 9. The strap 9 may have elastic properties to allow the strap 9 to stretch during removal of the cap 10 from the mouthpiece 4.

Advantageously, the first moulding, comprising the housing 2, incorporating the cylindrical portion 3 and the mouthpiece 4, may be made from a relatively inexpensive material such the currently used polypropylene and moulded relatively quickly since the wall sections are relatively uniform and slight degrees of distortion are acceptable. This allows for a short moulding cycle to be used which reduces the component cost. The first moulding can be made from a variety of other plastic materials, particularly if some other functional property such as transparency is required.

The second moulding, comprising the valve stem 5 in the first embodiment and the valve stem block 5, strap 9 and cap 10 in the second embodiment, may be manufactured from different materials having improved moulding characteristics such as polypropylene or polyester or nylon or other engineering plastic for the first embodiment and polypropylene or polyester or nylon or other engineering plastic or a thermoplastic elastomer or a combination of these for the second embodiment. In addition, the cycle time for the second moulding may be adjusted to improve the dimensional tolerances and reduce distortion to allow for precise moulding of the bore 6 and spray orifice 13. Advantageously, the more accurate moulding allows for a smaller spray orifice to be formed consistently and accurately. Spray orifice diameters down to 0.10 mm are possible. Whilst the cycle time for the second moulding is longer than that for the first moulding, the component is smaller and therefore more components may be located within a single mould tool which reduces the cost.

An advantage of the second embodiment of the second moulding is that it provides a means of simultaneously producing by moulding the dust cap 10 with the valve stem block 5 and the attaching strap 9 whereby each of these parts can be moulded in a different material, the choice being governed by the accuracy and properties required by each element of this integral moulding.

In both embodiments of the second moulding it is possible to produce the stem block 5 without a spray orifice 7 and to manufacture the spray orifice 7 as a secondary manufacturing operation by means such as laser drilling before the stem block 5 is assembled to the first moulding. The relatively small size of the first embodiment of the second moulding eases the handling and precision positioning required prior to

Claims:

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1. Dispensing apparatus for use with a pressurised dispensing container comprising a housing defining a socket or receiss for receiving, in use, a pressurised dispensing container: a mouthpiece; and a valve stem receiving means defining a bore for receiving, in use, a valve stem of a pressurised dispensing container; wherein the housing is formed from a first moulding and the valve stem receiving means is formed from a second moulding, the first and second mouldings being assemblable to form the dispensing apparatus.

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- Dispensing apparatus as claimed in claim 1
 wherein the first and second mouldings are made from different materials.
- Dispensing apparatus as claimed in claim 1 or claim 2 wherein securing means are provided to secure the first and second mouldings together in their assembled condition.
- Dispensing apparatus as claimed in claim 3 in which the securing means comprises cooperating snapfit formations, mechanical fasteners, adhesives and/or welds
- Dispensing apparatus as claimed in any preceding claim wherein the second moulding further comprises a cap for closing the mouthpiece, the cap being attached to the valve stem receiving means.
- 6. Dispensing apparatus as claimed in any preceding claim wherein a spray orifice is provided in the valve stem receiving means through which product from a pressurised dispensing container is discharged towards the mouthpiece, wherein the spray orifice has a

performing the secondary manufacturing operation.

diameter of 0.10 to 0.40 mm.

 Dispensing apparatus as claimed in claim 6 wherein the spray orifice has a diameter of 0.15 mm to 0.25 mm.

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- 8. Dispensing apparatus as claimed in any preceding claim wherein the first moulding is of polypropylene.
- 10 9. Dispensing apparatus as claimed in any preceding claim wherein the second moulding is of polyester, nylon or a thermoplastic elastomer or a combination thereof.
- 15 10. Dispensing apparatus as claimed in claim 8 or claim 9 further comprising another engineering plastic.
- 11. A method of manufacturing a dispensing apparatus for use with a pressurised dispensing container comprising the steps of making a first moulding which comprises a housing defining a socket or recess for receiving in use a pressurised dispensing container and a mouthpiece, making a second moulding which
- 5 comprises a valve stem receiving means defining a bore for receiving in use a valve stem of a pressurised dispensing container, and assembling the first and second mouldings to form the dispensing apparatus.
- 10 12. A method as claimed in claim 11 wherein the first and second mouldings are secured together in the assembled condition by securing means.
- A method as claimed in claim 12 in which the securing means comprise cooperating snap-fit formations, mechanical fasteners, adhesives and/or welds.

- 14. A method as claimed in any of claims 11 to 13 wherein a spray orifice is formed during the second moulding step.
- 5 15. A method as claimed in any of claims 11 to 13 wherein a spray orifice is formed after the second moulding step by means of a secondary manufacturing operation such as laser drilling.
- 16. Apparatus substantially as hereinbefore described with reference to or as shown in the accompanying drawings.
- 17. A method substantially as hereinbefore described with reference to or as shown in the accompanying drawings.







Application No:

GB 0022115.0

Reaminer: Susan Chalmers (Mrs)
Date of searth: 14 February 2001

Patents Act 1977 Search Report under Section 17

Databases searched:

Chims searched: 1-17

UK Patent Office collections, including GB, EP, WO & US patent specifications, in: UK CI (Ed.S): AST: TBE

Int C1 (Ed.7): A61M: 15/00 Other: ONLINE: EPODOC, WPI, JAPIO

aideand to be relevant:

Category	Identity of document and relevant passage		
х	GB 2322804 A	(BESPAK) see nozzle block 20 in Figure 1 and	1,3,4,6,11- 14 at least 1,3,4,6,7,1
x	GB 2170430 A	(RYFORD) see especially Figures 2 and 3 and page 1 lines 9-10 and 54-63	1-14 at least
x	GB 1021739	(MERCK) see eg Figures 2-5	1,3,4,6,7,1 1-14 at least
x	WO 99/25406 A	(ASTRA) see eg nozzie block 20 in Figures 9-16, page 1 lines 6-24 and page 2 lines 2-11	1-4,6-10
x	US 3818908	(PHILLIPS) see eg parts 11,12,15 in Figures 1-2 and column 2 lines 27-48	1,3,4,6,7, 1-14 at least

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